



November 13, 2000

Dockets Management Branch (HFA-3057) '00 NOV 14 19:06
Food and Drug Administration
5630 Fishers Lane, Rm.1061
Rockville, MD 20852

Ladies and Gentlemen:

Re: Comments on Proposed Rule "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use"

We refer to your proposed rule from the Federal Register of September 19, 2000 (Docket No. 00N-1463), that would require all systemic antibacterial drug products intended for human use to contain additional labeling information about the emergence of drug-resistant bacterial strains.

We concur that the appropriate and judicious use of antibiotics is of vital concern. We support efforts to increase the awareness of physicians and the public of the problem of antimicrobial resistance and what can be done to limit the emergence of further resistance.

As the marketer of a parenteral antibiotic, Rocephin®, we agree with the proposed rule with one exception.

We specifically refer to the proposed addition to the "Precautions" section under "Information for Patients" stating: *"Patients should be counseled that (insert name of antibacterial drug product) should only be used to treat bacterial infections. It does not treat viral infections (e.g., the common cold). Patients should also be told that the medication should be taken exactly as directed. Skipping doses and not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop that will not be treatable by (insert name of antibacterial drug product) in the future."*

This statement applies only to drugs that are self-administered, not to antibiotics that are administered by a skilled caregiver. Thus, we believe that this statement does not apply to parenteral antibiotic therapy and should not be included in the label for any antibiotic administered solely via intravenous or intramuscular routes.

Should you have any questions or which further information, please contact the undersigned.

Sincerely,

HOFFMANN-LA ROCHE INC.

Melanie Bishop

Melanie Bishop
Program Director
Drug Regulatory Affairs
Phone (973) 562-2764
Fax (973) 562-3700

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Hoffmann-La Roche Inc.

340 Kingsland Street
Nutley, New Jersey 07110-1199

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HOFFMANN-LA ROCHE INC
340 KINGSLAND STREET
BUILDING ONE, 2ND FLOOR
NUTLEY, NJ, 07110

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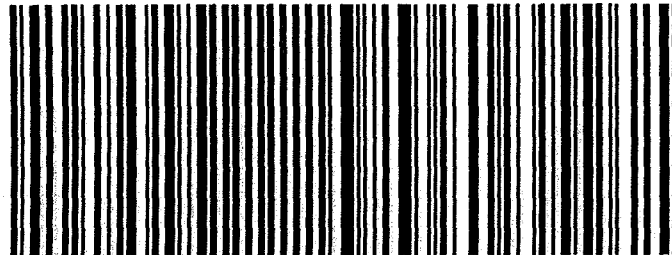
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